

(3) May extend the initial 15-day period for an additional 15 days if—

- (i) the MCO submits a written request that includes a credible explanation of why it needs additional time;
- (ii) the request is received by CMS before the end of the initial period; and
- (iii) CMS has not determined that the MCO's conduct poses a threat to an enrollee's health or safety.

(d) *Informal reconsideration.* (1) If the MCO submits a timely response to the notice of sanction, the State agency—

- (i) Conducts an informal reconsideration that includes review of the evidence by a State agency official who did not participate in the original recommendation;

- (ii) Gives the MCO a concise written decision setting forth the factual and legal basis for the decision; and

- (iii) Forwards the decision to CMS.

(2) The agency decision under paragraph (d)(1)(ii) of this section becomes CMS's decision unless CMS reverses or modifies the decision within 15 days from date of receipt by CMS.

(3) If CMS reverses or modifies the State agency decision, the agency sends the MCO a copy of CMS's decision.

(e) *Denial of payment.* (1) CMS, based upon the recommendation of the agency, may deny payment to the State for new enrollees of the HMO under section 1903(m)(5)(B)(ii) of the Act in the following situations:

- (i) If a CMS determination that an MCO has acted or failed to act, as described in paragraphs (b)(1) through (b)(6) of § 438.700, is affirmed on review under paragraph (d) of this section.

- (ii) If the CMS determination is not timely contested by the MCO under paragraph (c) of this section.

(2) Under § 438.726(b), CMS's denial of payment for new enrollees automatically results in a denial of agency payments to the HMO for the same enrollees. (A new enrollee is an enrollee that applies for enrollment after the effective date in paragraph (f)(1) of this section.)

(f) *Effective date of sanction.* (1) If the MCO does not seek reconsideration, a sanction is effective 15 days after the date the MCO is notified under paragraph (b) of this section of the decision to impose the sanction.

(2) If the MCO seeks reconsideration, the following rules apply:

- (i) Except as specified in paragraph (d)(2)(ii) of this section, the sanction is effective on the date specified in CMS's reconsideration notice.

- (ii) If CMS, in consultation with the State agency, determines that the MCO's conduct poses a serious threat to an enrollee's health or safety, the sanction may be made effective earlier than the date of the agency's reconsideration decision under paragraph (c)(1)(ii) of this section.

(g) *CMS's role.* (1) CMS retains the right to independently perform the functions assigned to the State agency under paragraphs (a) through (d) of this section.

(2) At the same time that the agency sends notice to the MCO under paragraph (c)(1)(i) of this section, CMS forwards a copy of the notice to the OIG.

(3) CMS conveys the determination described in paragraph (b) of this section to the OIG for consideration of possible imposition of civil money penalties under section 1903(m)(5)(A) of the Act and part 1003 of this title. In accordance with the provisions of part 1003, the OIG may impose civil money penalties on the MCO in addition to, or in place of, the sanctions that may be imposed under this section.

Subpart J—Conditions for Federal Financial Participation

§ 438.802 Basic requirements.

FFP is available in expenditures for payments under an MCO contract only for the periods during which the contract—

- (a) Meets the requirements of this part; and
- (b) Is in effect.

§ 438.806 Prior approval.

(a) *Comprehensive risk contracts.* FFP is available under a comprehensive risk contract only if—

- (1) The Regional Office has confirmed that the contractor meets the definition of an MCO or is one of the entities described in paragraphs (b)(2) through (b)(5) of § 438.6; and

- (2) The contract meets all the requirements of section 1903(m)(2)(A) of the Act, the applicable requirements of